

It is believed that the claims as now written clearly avoid the rejection under 35 USC 112. They define specific amounts of all recited ingredients of the compositions except for the vitamin B₁₂, the buffer and the thickening agent. The amount of B₁₂ is recited as "therapeutically" effective. The amount of buffer is defined as the amount which provides a pH of from 4 to 6. The amount of thickening agent is described as the amount which will provide a viscosity of from about 2500 to 10,000 cps. It is submitted that the chosen terms adequately define the amounts of each ingredient in the nasal compositions, and will be fully understood by those skilled in the art.

The buffer and thickening agent have been further defined as pharmaceutically acceptable. There are a large number of buffers and thickening agents which are pharmaceutically acceptable. Applicant has mentioned and specifically illustrated several of them. There are, of course, others which are known to those skilled in the art, and are pharmaceutically acceptable and capable of providing compositions with the desired pH and viscosity. The selection of buffering agent and thickening agent is not the essence of this invention. It is immediately apparent to the skilled artisan that several such agents, other than those mentioned and/or illustrated can be employed in the invention to produce compositions of the desired pH and viscosity.

Support for the viscosity range appears in the second paragraph on page 4 of the specification.

Applicant's attorney wishes to thank Examiner Robinson for the courtesies extended at the interview on August 25, 1987. The interview was attended by Doctor Jeffrey Wenig, the inventor and the president of the company which is the assignee of record, and by Dr. Vincent Romeo who is Research Director of the company.

At the interview the rejection of the claims under 35 USC 112 was briefly discussed. It is understood that the examiner agrees that the claims as presented meet the requirements of the statute.

The rejection of the claims under 35 USC 103 over Diehl and Shinton et al when taken in view of Bargigia et al was extensively discussed.

Applicants submitted a copy of the Shinton et al article which the examiner previously had available only in abstract form. It was pointed out that the compositions described in the article were intended for inhalation into the alveoli and that the authors themselves concluded that parenteral administration

of vitamin B₁₂ was better than inhalation since the latter method resulted in the deposition of cobalt in the alveoli which brought about a toxic condition similar to heavy metal diseases.

In contrast applicant's compositions were designed to stay in the nasal cavity until substantially all of the B₁₂ had been absorbed. Applicant's compositions were, therefore, therapeutically useful. The inhalation compositions of Shinton et al were not.

This latter fact also distinguishes applicant's compositions from Diehl since the latter compositions are also designed as aerosols for absorption in the pulmonary area.

The secondary reference does not compensate for the deficiencies of the primary references and was used by the examiner only to show the use of thickening agents in propellant compositions.

Applicant's compositions in contrast to the compositions of the references are specifically designed for nasal administration to permit absorption of vitamin B₁₂ through the nasal mucosa for systemic distribution. The efficacy of the compositions is illustrated in the examples of the specification.


It is submitted that in view of the above amendments and remarks this application is now in condition for allowance. Prompt issuance of a notice of allowance is earnestly solicited.

There is enclosed herewith a check in the amount of \$85.00 in payment of the extension fee for response within the second month, this paper serving to confirm the petition for extension pursuant to the provisions of 37 CFR 1.136(a).

Kindly charge any additional fees or credit any overpayment to my deposit account number 02-4748.

The deficiencies of the drawings have been noted. It is requested that for convenience, the actual making of the corrections be postponed until there is an indication of allowance.

Respectfully submitted,


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